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| 10/576,803 | 04/21/2006 | Mary J. Champion | D-3150 | 5915 |

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| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/576,803 | CHAMPION, MARY J. | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33,35,36,38,39,41,44,45 and 55-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33, 35, 36, 38, 39, 41, 44, 45, 55-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 03/23/2007; and amendment filed 07/03/2007.

Claims 1-32, 34, 37, 40, 42, 43 and 46-54 have been canceled.

Claims 33, 35, 36, 38, 39, 41, 44, 45, 55-66 are pending and included in the prosecution.

**The following rejections have been overcome by virtue of applicant's amendment and remarks:**

The rejection of claims 39, 60 and 66 under 35 U.S.C. 112, second paragraph, as being indefinite.

**The following new ground of rejection is necessitated by applicant's amendment:**

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 39, 60 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to the claims to recite "adjacent the water containing gel" has introduced new matter not described by the original specification. The term adjacent means "to lie near or close to", and it is not clear from the disclosure or the figures how the border is near or close to the water containing gel layers as claimed by claim 39, or how the strips are near or close to the water containing gel as claimed by claims 60 and 66. Figure 3 indicates border 26 that surrounds the cooling component 18, and not adjacent to water containing gel. In description of figure 7, page 16, 1st paragraph of the present specification, applicant states that: "border 226 which is free of the cooling component". However, recourse to figure 7, nothing is illustrated by number 226. Regarding adjacent strips, nowhere in the present specification or figures applicant disclosed strips neat or close to the water containing gel and how the strips are located near by or close to the water containing gel.

**The following rejection and objections have been discussed in the previous office action, and are maintained for reasons of record:**

***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant has not indicated review and correction to the specification, therefore this objection is maintained.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 33, 35, 36, 38, 41, 44, 45, 55-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the presentation prepared by Kobayashi Healthcare, INC.: "Product Concept Test", hereinafter Kobayashi, in view of any of JP 2002119529 ('529) or US 6,224,899 ('899).

Kobayashi article disclosed cooling gel sheet used for treating hot flashes. The article implies that the gel sheets been in use before the article date August 14, 2003. hot flashes are known as symptoms associate the menopause syndrome. The article does not teach any active agent in the gel sheet.

Kobayashi article does not teach packaging and instructing the user to apply the cooling gel sheet at a location on specific site as claimed by claims 33, 44, 45, 55 and 61. Kobayashi article does not teach structure of the cooling device as comprising water containing gel comprising polyacrylic component and gas permeable substrate as claimed by claims 35, 36, 38, 57-59, 63-65, or the package are claimed by claims 56 and 61.

Regarding the package and instruction, it is not patentable limitation in utility application. The instruction to apply the patch at specific site does not impart patentability to the claims because it is expected that the patch will be applied to the site of origin of hot flashes as disclosed by applicant on page 9, lines 1-5. With regard to the package, the package does not impart patentable weight absent functional relationship between the package and the product, and because the product still function equally effectively with or without the package. Packaging is obvious and well known in the pharmaceutical art.

JP '529 teaches cooling patch which can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, said patch comprises water permeable film covered with hydrous paste of polyacrylic acid (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-

61). The cooling patch can be applied locally to the area of discomfort without limitation to the body part such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes as disclosed by Kobayashi article, and made the sheet of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by JP '529 or US '899, motivated by the teaching of JP '529 that such a cooling patch structure and materials can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, or motivated by the teaching of US '899 that such an adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue, with reasonable expectation of having cooling patch or sheet comprising water permeable backing and polyacrylic acid paste or gel that is able to maintain the cooling effect and preserve the coolness of the site of its application to treat hot flashes successfully and effectively.

6. Claims 33, 35, 36, 38, 41, 44, 45, 55-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '529 or US '899 each in view of US 5,730,957 ('957).

The teachings of JP '529 and US '899 are discussed above.

The references do not teach providing instruction the user as claimed by claims 33, 44, 45, 55 and 61, or the package as claimed by claims 56 and 61.

Regarding the instruction, it is not patentable limitation in utility application. The instruction to apply the patch at specific site does not impart patentability to the claims because it is expected that the patch will be applied to the origin site of hot flashes, as disclosed by applicant on page 9, lines 1-5. With regard to the package, the package does not impart patentable weight absent functional relationship between the package and the product, and because the product still function equally effectively with or without the package.

Although JP '529 and US '899 teach cooling devices applied at the site of pain or fever, the references do not explicitly teach treating hot flashes.

US '957 teaches cooling mixture used for cooling the body to treat medical conditions such as fever, to offer heat relief for those who experience hot flashes, and relief muscular strain (abstract; col.5, line 6 till col.6, line 18). Therefore, the art recognized using cooling technique to treat fever, hot flashes, and muscle stain equally. In other words, the art recognized the equivalency between fever, hot flashes, and muscle stain, in terms of treating them using the same cooling methods and devices.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat fever, muscle strain or pain using cooling devices comprising aqueous gel and permeable backing as disclosed by JP '529 or US '899, and further use such devices to treat hot flashes as disclosed by US '957, motivated by the teaching of US '957 that the cooling mixtures that treat fever and muscle strains will

effectively offer heat relief for those who experience hot flashes, with reasonable expectation of having cooling devices comprising aqueous gel and permeable backing offering heat relief for those who experience hot flashes with great success.

7. Claims 39, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of article by Kobayashi with of any of JP 2002119529 ('529) or US 6,224,899 ('899) and further in view of US 3,811,438 ('438).

The combines teachings of Kobayashi with either JP '529 or US '899 are discussed above.

However, the combined teachings of the references do not teach strips of adhesive located over the gel that is substantially free of adhesive as claimed by claims 39, 60 and 61.

US '438 teaches an adhesive bandage comprising a backing layer coated with continuous adhesive layer covered by strips of adhesive having less adhesiveness to provide bandage that readily removable with reduced pain or discomfort of the user (col.1, lines 45-49; co1.3, lines 65-68; co1.4, lines 1-3, 38-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes comprising of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by the combined teachings of Kobayashi article with JP '529 or US '899, and further add strips of less adhesiveness on/around the paste or gel as disclosed by US '438, motivated by the teaching of US '438 that such the presence of two adhesiveness of

different adhesiveness strength provide bandage that readily removable with reduced pain or discomfort of the user, with reasonable expectation of having cooling gel patch to treat hot flashes having strips of adhesives with different adhesiveness strength that is readily removable with reduced pain or discomfort of the user.

8. Claims 39, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of any of JP 529 or US '899 each with US '957, and further in view of US '438.

The combined teachings of JP '529 and US '899, each with US '957 are discussed above.

However, the combined teachings of the references do not teach strips of adhesive located over the gel that is substantially free of adhesive as claimed by claims 39, 60 and 61.

US '438 teaches an adhesive bandage comprising a backing layer coated with continuous adhesive layer covered by strips of adhesive having less adhesiveness to provide bandage that readily removable with reduced pain or discomfort of the user (col.1, lines 45-49; co1.3, lines 65-68; co1.4, lines 1-3, 38-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes comprising of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by the combined teachings of JP '529 or US '899 with US '957, and further add strips of less adhesiveness on/around the paste or gel as disclosed by US '438, motivated by the

teaching of US '438 that such the presence of two adhesiveness of different adhesiveness strength provide bandage that readily removable with reduced pain or discomfort of the user, with reasonable expectation of having cooling gel patch to treat hot flashes having strips of adhesives with different adhesiveness strength that is readily removable with reduced pain or discomfort of the user.

***Response to Arguments***

9. Applicant's arguments filed 07/03/2007 have been fully considered but they are not persuasive. The main gist of applicant's argument against the obviousness rejections above is that none of the references teaches method for treating hot flashes comprising placing cooling device comprising water containing gel at a location on the upper back of a women. Applicant argues that the references do not disclose the method comprises the steps of removing at least one cooling device from a package and placing it on the upper back. Applicant argues that JP '529 and US '899 treats localized lesions and not systemic conditions as hot flashes, and not on the upper back. The combined teaching of the references would not teach the present method for treating hot flashes. Applicant argues that US '957 does not teach method for treating hot flashes by instructing women to place cooling device in the upper back, and argues that US '957 teaches spray. Applicants argue that US '438 teaches bandage, and does not teach the claimed method for treating hot flashes.

In response to these argument, applicant's attention is directed to the scope of the present claims that are directed method of treating hot flashes comprising the steps of providing one cooling device, and instructing the patient. The step of providing the cooling device is implied by all the references. Regarding the "instructing step", such a step not patentable limitation in utility application. The instruction to apply the patch at specific site does not impart patentability to the claims because it is expected that the patch will be applied to the site of origin of hot flashes as disclosed by applicant on page 9, lines 1-5. With regard to applicant argument that the prior art does not teach the package, it is argued that the package does not impart patentable weight absent functional relationship between the package and the product, and because the product still function equally effectively with or without the package. Packaging is obvious and well known in the pharmaceutical art. In any event, the package, the instruction, and removing the cooling device from the package are obvious and are evident by the pamphlet provided by "BeKOOL soft gel sheet product", provided. Also the provided pamphlet shows drawing wherein the sheet is applied to the upper back in a woman with hot flashes.

Regarding JP '529 and US '899, the references are relied upon for teaching the structure of the cooling device and its application to the site need cooling. Applicant desired to apply the cooling device to the hot flash origin site, and JP '529 and US '899 both teach applying the cooling device to the area needs cooling. US '957 is relied upon for teaching the equivalency between hot flashes, fever, and muscle pain, and to show

that such conditions are treated effectively using local cooling at the site of origin of the hot feeling, as desired by applicant.

The combined teaching of the references would have taught treating hot flashes, because Kobayashi taught treat hot flashes using cooling gel patch, and JP '529 and US '899 are relied upon for teaching the site of application that follows the origin of the hot feeling as desired by applicants. US '957 is relied upon for teaching equivalency between fever, hot flashes and muscle sprain.

Regarding US '438, the reference is relied upon for the solely teaching of limitations of claims 39, 60 an d66 that recite the strips and border that is devoid of the cooling gel. US '438 does not need to teach the limitations of the method that are taught by the other references.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,956,963 disclosed treatment of hot flashes using wrist cooler.

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
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PRIMARY EXAMINER